

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the PROFEMUR® GLADIATOR® HA Hip Stems.

<b>Submitted By:</b>	Wright Medical Technology, Inc. 5677 Airline Rd, Arlington TN, 38002 (800) 238-7188
<b>Date:</b>	July 22, 2011
<b>Contact Person:</b>	Matt Paul <i>Project Regulatory Affairs Specialist</i>
<b>Proprietary Name:</b>	PROFEMUR® GLADIATOR® HA Hip Stem
<b>Common Name:</b>	Hip Stem
<b>Classification Name and Reference:</b>	21 CFR 888.3330 Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis Class III
<b>Subject Product Code and Panel Code:</b>	Orthopedics/87/KWA, JDL, LZO
<b>Predicate Devices Name and Number:</b>	PROFEMUR® Hip System Modular Necks PROFEMUR® Z PROFEMUR® Hip System PROFEMUR® TL Hip Stem PROFEMUR® Renaissance HA CORAIL® Hip Prosthesis  510(k): K100866, K091423, K021346, K012091, K060358, K051995, K953111, K042992
<b>Predicate Classification and Number:</b>	Orthopedics/87/ KWA, 888.3330

**DEVICE INFORMATION****A. Device Description**

The PROFEMUR® GLADIATOR® HA stems are hydroxyapatite coated hip stems that couple with modular necks. Design features of the stems are summarized below:

- Cementless stem with hydroxyapatite plasma spray coating
- Available in 10 sizes
- Manufactured from Ti alloy (Ti-6Al-4V) conforming to ASTM F620
- Hydroxyapatite coating conforming to ASTM F1185
- Available with and without collar

K112150

The PROFEMUR® GLADIATOR® HA Hip Stems were evaluated via mechanical testing; including fatigue, fretting, and distraction evaluation. A review of these results indicates that the GLADIATOR® HA Hip Stems are equivalent to predicate devices and are capable of withstanding expected *in vivo* loading without failure.

**B. Intended Use**

The PROFEMUR® GLADIATOR® HA Hip Stems are intended for use in uncemented total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

**Indications for Use**

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

The PROFEMUR® GLADIATOR® HA hip stem is intended for cementless hip arthroplasty.

**C. Technological Characteristic of the Device**

The PROFEMUR® GLADIATOR® HA Hip Stems have the same technological characteristics as the predicate device. PROFEMUR® GLADIATOR® HA Hip Stems are straight uncemented hip stems with a modular design. They feature a proximal trapezoidal cross-section and a distal rectangular cross-section. For fixation stability in three planes, the stem has a vertically tapered profile in the frontal and lateral planes. The materials used for the PROFEMUR® GLADIATOR® HA Hip Stems are identical to the materials used for the predicate devices.

**D. Nonclinical Testing**

The PROFEMUR® GLADIATOR® HA Hip Stems have been tested in distal and proximal fatigue evaluation per the loading regimen prescribed by ISO 7206-4, -6 and -8.

**E. Clinical Testing**

Clinical data was not provided for the class III hip stem.

**F. Conclusions**

The indications for use of the PROFEMUR® GLADIATOR® HA Hip Stems are identical to the previously cleared predicate devices. The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. The safety and effectiveness of the PROFEMUR® GLADIATOR® HA Hip Stems are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

Wright Medical Technology, Inc.  
% Mr. Matt Paul  
5677 Airline Rd.  
Arlington, TN 38002 US

NOV 23 2011

Re: K112150

Trade/Device Name: Profemur Gladiator HA Hip Stem  
Regulation Number: 21 CFR 888.3330  
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.  
Regulatory Class: Class III  
Product Code: KWA, JDL, LZO  
Dated: November 18, 2011  
Received: November 21, 2011

Dear Mr. Matt Paul:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Mark N. Melkerson

Director

Division of Surgical, Orthopedic & Restorative Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K112150

Device Name: PROFEMUR®Gladiator HA Hip Stems

### Indications For Use:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

The PROFEMUR® Gladiator HA Hip Stem is intended for cementless hip arthroplasty.

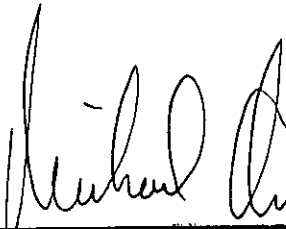
Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

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